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# Performance of Portable Ventilators at Temperature Extremes

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In the current theater of operation, medical devices are often shipped and stored at ambient conditions. The effect of storage at hot and cold temperature extremes on ventilator performance is unknown. We evaluated three portable ventilators currently in use or being evaluated for use by the Department of Defense (731, Impact Instrumentation; T1, Hamilton Medical; and ReVel, CareFusion) at temperature extremes in a laboratory setting. The ventilators were stored at temperatures of 60°C and -35°C for 24 hours and were allowed to acclimate to room temperature for 30 minutes prior to evaluation. The T1 required an extra 15-30 minutes of acclimation to room temperature before the ventilator would deliver breaths. All delivered tidal volumes at room temperature and temperature extremes were less than the ±10% American Society for Testing and Materials standard with the ReVel. Delivered tidal volumes at the pediatric settings were less than the ±10% threshold at both temperatures and at room temperature with the 731. Storage at extreme temperature affected the performance of the portable ventilators tested. This study showed that portable ventilators may need an hour or more of acclimation time at room temperature after storage at temperature extremes to operate as intended.

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## 1.0 SUMMARY

In the current theater of operation, medical devices are often shipped and stored at ambient conditions. The effect of storage at hot and cold temperature extremes on ventilator performance is unknown. We evaluated three portable ventilators currently in use or being evaluated for use by the Department of Defense (731, Impact Instrumentation; T1, Hamilton Medical; and ReVel, CareFusion) at temperature extremes in a laboratory setting. The ventilators were stored at temperatures of 60°C and -35°C for 24 hours and were allowed to acclimate to room temperature for 30 minutes prior to evaluation. The T1 required an extra 15-30 minutes of acclimation to room temperature before the ventilator would deliver breaths. All delivered tidal volumes at room temperature and temperature extremes were less than the ±10% American Society for Testing and Materials standard with the ReVel. Delivered tidal volumes at the pediatric settings were less than the ±10% threshold at both temperatures and at room temperature with the 731. Storage at extreme temperature affected the performance of the portable ventilators tested. This study showed that portable ventilators may need an hour or more of acclimation time at room temperature after storage at temperature extremes to operate as intended.

## 2.0 BACKGROUND

In the current theater of military operations and in disaster situations, medical devices are often shipped and stored at room temperatures. These devices may be operated with little time to acclimate to room temperature. The effect of storage at temperature extremes on ventilator performance is unknown, and to our knowledge no evaluations of these effects in modern devices have been published. Safe ventilator support of patients requires ventilators deliver desired settings accurately.

Consistent tidal volume ($V_T$) is of critical importance, especially in patients with acute respiratory distress syndrome as shown by the results of the Acute Respiratory Distress Syndrome Network study showing that using low $V_T$ (6 mL/kg of predicted body weight) improved mortality [1]. Other ventilator settings such as respiratory rate and positive end expiratory pressure (PEEP), if altered, may lead to acid-base imbalance and hypoxemia and/or hemodynamic instability, respectively. We evaluated, at temperature extremes, the performance of three portable ventilators currently used or are being considered for use during military operations.

## 3.0 METHODS

We evaluated three commercially available portable ventilators: 731 (Impact Instrumentation, West Caldwell, NJ), T-1 (Hamilton Medical, Reno, NV), and ReVel (Carefusion, San Diego, CA) in a laboratory setting. Studies were conducted in an altitude/environmental chamber at the University of Cincinnati. The devices were stored at temperatures of 60°C and -35°C in the chamber for 24 hours and operated after placement outside the chamber at room temperature for 30 minutes. Room temperature was 21°C. We used the Department of Defense Test Method Standard (MIL-STD-810G) [2] and Joint Enroute Care Equipment Test Standard [3] as guidance in selecting the testing temperatures.

After storage at each temperature for 24 hours and 30-minute acclimation to room temperature, ventilators were connected to AC power, attached to a two-chamber test lung (TTL, Michigan Instruments, Grand Rapids, MI) via the manufacturer-supplied circuit, and evaluated using the combinations of ventilator settings shown in Table 1 using pediatric and adult lung models shown in Table 2. A Fleisch pneumotachograph (Series 4700, Hans Rudolph, Shawnee, KS) was connected between the ventilator circuit and the test lung, and the signals for airway pressure, flow, and volume were collected on a breath-to-breath basis by a research data collection system (RSS 100, Hans Rudolph, Shawnee, KS) and recorded to a PC for later analysis. The pneumotachograph was calibrated before each set of measurements using a 3-liter super syringe. We recorded the time from powering on the ventilator until satisfactory operation. After a 1-minute stabilization period, a minimum of 1 minute of data was collected at each combination of lung model and ventilator settings. All tests were performed at each temperature a minimum of two times. Delivered and set $V_T$s were compared using the American Society for Testing and Materials (ASTM) standard of ±10% of set $V_T$ [4].

**Table 1. Pediatric and Adult Ventilator Settings Used in the Evaluation**

| Lung Model | Respiratory Rate | Tidal Volume (mL) | PEEP (cm $H_20$) | $FIO_2$[a] |
|---|---|---|---|---|
| Pediatric | 30 | 50 & 100 | 0 & 10 | 0.21 & 1.0 |
| Adult | 15 | 500 & 750 | 0 & 20 | 0.21 & 1.0 |

[a]$FIO_2$ = fraction of inspired oxygen.

**Table 2. Pediatric and Adult Lung Models**

| Lung Model | Lung Compliance | Airway Resistance |
|---|---|---|
| Pediatric | 0.01 L/cm $H_2O$ | 20 cm $H_2O$/L/s |
| Adult Normal | 0.1 L/cm $H_2O$ | 5 cm $H_2O$/L/s |
| Adult Restrictive | 0.02 L/cm $H_2O$ | 5 cm $H_2O$/L/s |

A paired t-test was performed with each at each combination of settings and lung models to determine if there were statistical differences in delivered $V_T$s when comparing the room temperature measurements to the same measurements after storage at -35°C and 60°C. Statistical significance was a $p < 0.05$.

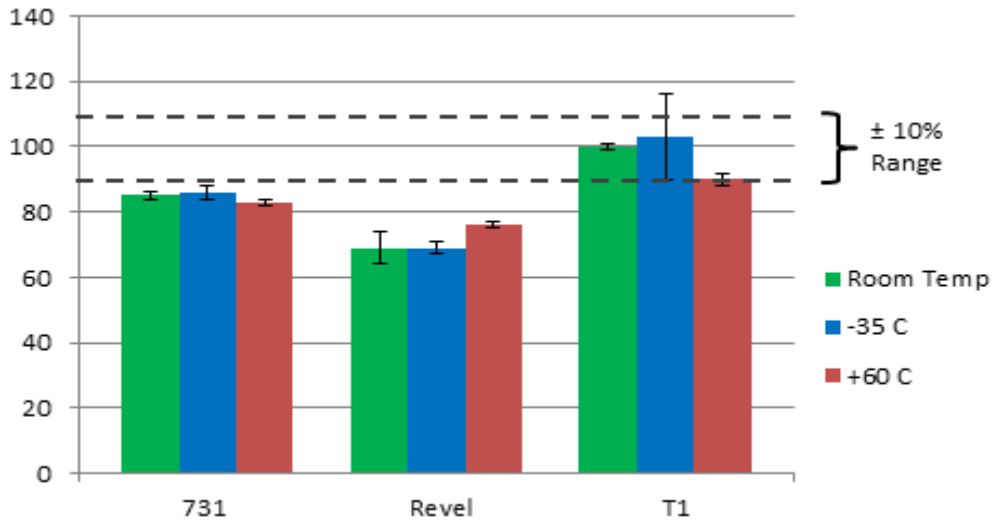
## 4.0 RESULTS

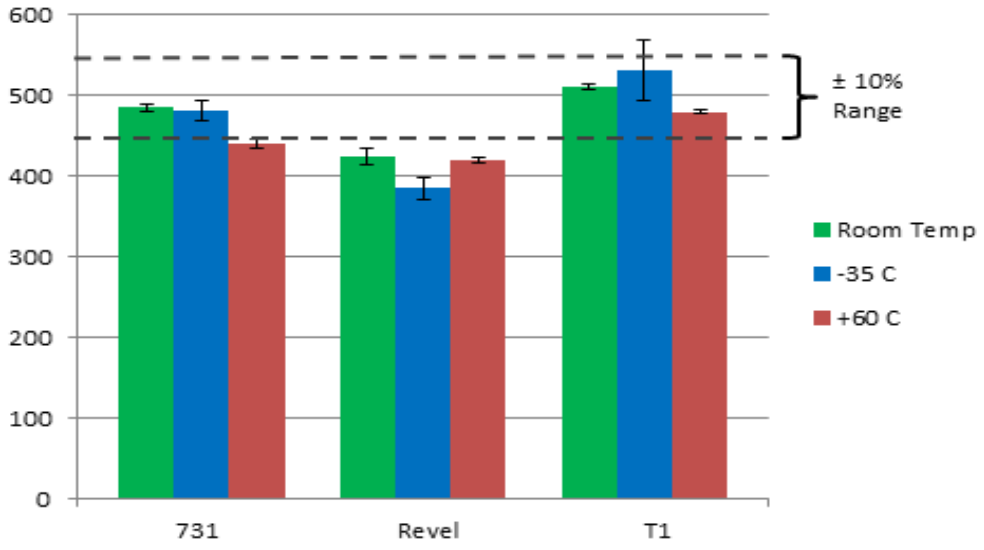
Operation and/or performance was affected by storage at temperature extremes with all the ventilators tested. The T1 required an additional 15-30 minutes (45-60 minutes total) of time to acclimate to room temperature before the ventilator would begin delivering breaths. Additionally, at both the high and low temperatures, the T1 pressure limited at pressures less than 50 cm $H_2O$ with the 750-mL settings despite the high pressure limit setting of 70 cm $H_2O$, therefore failing to deliver the full $V_T$. At all other conditions, the T1 delivered $V_T$s within the 10% threshold throughout the range of settings. Differences in delivered $V_T$ from room

temperature measurements were statistically significant at all settings except the 100-mL and 250-mL $V_T$ settings after storage at -35°C.

After storage at both temperature extremes, the 731 operated immediately after 30 minutes of acclimation to room temperature but displayed either a "battery too hot" or "battery too cold" alert at each of the respective temperatures. Delivered $V_T$s at the pediatric settings were less than the ±10% threshold at both temperatures and at room temperature. The maximum decrease from the set $V_T$ was 17% at the 100-mL setting following cold storage. The adult delivered $V_T$s were within ±10% of the set $V_T$ at room temperature and after storage at both temperature extremes. Delivered $V_T$s were statistically different from room temperature measurements with all settings except at 500 mL, 0 cm $H_2O$ PEEP, at a lung compliance of 20 mL/cm $H_2O$, and 750 mL, 20 cm $H_2O$ PEEP, at a lung compliance of 20 mL/cm $H_2O$ after storage at -35°C.

The ReVel began operating immediately after 30 minutes of acclimation to room temperature following extreme temperature storage. There were no alarms or alerts displayed concerning battery temperature or ability to deliver the ventilator settings chosen. The delivered $V_T$s in both the pediatric and adult settings were all less than the ASTM ±10% range at room temperature and both temperature extremes. Figures 1 and 2 show delivered $V_T$ as compared to the ± ASTM standard at room temperature and both temperature extremes using the 100-mL pediatric and 500-mL adult settings, respectively. Nearly half of the delivered $V_T$s after storage at -35°C were statistically different from room temperature measurements. Delivered $V_T$s at all pediatric settings were not statistically different after -35°C storage but were after storage at 60°C. All $V_T$s after storage at 60°C were statistically different from room temperature $V_T$s except at settings of 250 mL, 0 cm $H_2O$ PEEP and lung compliances of 20 and 100 mL/cm $H_2O$.






After storage at extreme temperatures, there were no alterations in set respiratory rate or inspiratory time. The addition of PEEP, using an $FIO_2$ of 1.0 or varying lung compliance, did not markedly alter delivered $V_T$s in any of the settings with any of the ventilators tested. The digital displays with each of the devices continued to operate appropriately during testing at all conditions. There was a tendency with all the devices for $V_T$s to decrease as compared to room temperature $V_T$s after storage at 60°C, although this did not result in the $V_T$s being outside the ±10% range at room temperature. Due to the number of measurements taken at each setting and the small variance between each measurement, many of the differences were statistically significant but not necessarily clinically significant. Clinical significance was determined by applying the ASTM ±10% standard as compared to the set $V_T$.

## 5.0 DISCUSSION

The main findings of the study demonstrate that following acclimation to room temperature, all three ventilators accurately delivered set $V_T$s. We also demonstrated that one of the ventilators required 45 minutes of stabilization before it would operate. While many of the differences in set and delivered $V_T$s were statistically significant, the clinical importance of these differences is negligible.

Devices that are designed for use under optimal conditions are often used in austere environments. During military conflicts, medical devices may be subject to storage temperatures that are outside the manufacturers' specifications. Therefore, the ability of the devices to perform under these conditions is unknown. Temperatures on Air Force flight lines can reach as high as 140°F (60°C) during the summer [5] and as low as -51°F (-46°C) during the winter [6]. Laboratories utilized by the branches of the military such as the Air Force Research Laboratory and United States Army Aeromedical Research Laboratory provide environmental testing covering a broad spectrum of harsh conditions in which a device may be deployed. Although the testing by these laboratories is rigorous, their main purpose is to determine if the device operates

after being subjected to these conditions, doesn't ignite, and doesn't emit electromagnetic signals that would interfere with the operation of an aircraft or reveal the position of the caregiver and casualty to the enemy. Clinical validation by evaluating and measuring the delivered parameters as compared to set parameters over a range of clinically relevant settings is not part of the testing regimen. Life-sustaining medical devices, such as the ventilators included in this study, must accurately provide the parameters set by the caregiver to ensure patient safety.

We conducted a comprehensive literature search and found four documents pertaining to testing of ventilation devices. Bruckart et al. [7] evaluated medical devices, including two portable ventilators at temperature extremes, based on MIL-STD-810D. The authors found that neither of the ventilators tested failed after storage at temperature extremes (63°C and -46°C). The details of the testing procedure, ventilator settings, or ventilator type or model were not provided in the publication. Barnes and Stockwell [8] evaluated the performance of 10 manual resuscitators at -18°C and 50°C. The results of the study showed that only two of the resuscitators met ASTM and International Organization for Standardization performance standards at both temperature extremes. The remaining two publications [9,10] evaluated five portable ventilators (Motivus, Pneupac 2, Logic 07, Oxylog, and Maxaman) at temperature extremes and found that although all the devices functioned well at high temperatures, only two would operate at temperatures below 0°C. The devices evaluated in these two studies are no longer commercially available.

The results of our study show ventilator storage at extremely cold or hot temperatures can be problematic for the newest generation of portable ventilators. Recommended storage temperatures reported in the operator's manuals of the devices were -15°C to 70°C with the T1 [11], -25°C to 49°C with the 731 [12], and -20°C to 60°C with the ReVel [13]. Additionally, the ReVel operator's manual states the device will operate at least 20 minutes when returned to room temperature for 10 minutes after storage at temperatures of -30°C to 70°C. Storage at extremely cold temperatures prevented the T1 from immediately starting up after the 30-minute warm-up period and altered performance as demonstrated by false high-pressure readings and alarms with the 750-mL $V_T$ settings. Even though we did not operate the ventilators on DC power, the high and low battery temperature alerts on the 731 warned that the temperature conditions were outside of the specifications. There were no such alerts with the T1 and ReVel, but the T1 "Technical Fault" alarms on startup after storage at -35°C were followed by codes; the cause, however, was not specified on the device or in the operator's manual. Despite the startup and battery problems associated with storage at extreme temperatures outside the ventilators' published temperature storage ranges, the delivered $V_T$s were not markedly different from those recorded at room temperature. Although the majority of the $V_T$ differences between room temperature and temperature extremes were statistically significant, with the exception of the ReVel and those detailed in the Results section with the T1 and 731, delivered $V_T$s were within 10% of the set $V_T$s across a range of settings.

## 6.0 CONCLUSIONS

Storage of medical devices at extremes in temperature is often necessary in the theater of operations in austere environments. After storage, devices must be able to acclimate to room temperature within a reasonable time frame and operate accurately as intended. Caregivers must have confidence that the device settings are reliably delivered to the patient. This study showed that portable ventilators may need an hour or more of acclimation time at room temperature after

storage at temperature extremes to operate as intended. Caregivers must be aware of the performance limitations when portable ventilators cannot be stored at optimal temperatures.

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## LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **ASTM** | American Society for Testing and Materials |
| **$FIO_2$** | fraction of inspired oxygen |
| **PEEP** | positive end expiratory pressure |
| **$V_T$** | tidal volume |